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IN THE

Supreme Court of the United States

OCTOBER TERM, 1979

No. 78-911

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.

No. 78-1036

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.

On Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

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BRIEF FOR THE AMICUS CURIAE CHAMBER OF COMMERCE OF THE UNITED STATES

Of Counsel

STEPHEN A. BOKAT
WILLIAM L. KOVACS
National Chamber Litigation Center
1615 H Street, N.W.
Washington, D.C. 20062

ROBERT V. ZENER
Pepper, Hamilton & Scheetz
1776 F Street, N.W.
Washington, D.C. 20006

Attorneys for Amicus Curiae
Chamber of Commerce of the United States

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BRIEF FOR THE AMICUS CURIAE CHAMBER OF COMMERCE OF THE UNITED STATES

INTEREST OF THE AMICUS CURIAE

The Chamber of Commerce of the United States is the largest business federation in the United States, consisting of over 3700 State and local chambers of commerce and trade and professional associations, and a direct business membership in excess of 81,000 business firms and individuals.

The present case is of vital concern to the Chamber's members, for four reasons.

First, the position taken by OSHA — that it may issue standards without any estimate of their effectiveness in benefiting worker health — will inevitably increase the already substantial costs imposed on American business by OSHA regulation. A recent study of OSHA's policy for regulation of carcinogens estimated that it will result in $9 to 88 billion capital costs and $6 to 36 billion annual costs, depending on how it is applied.[1]

Second, the Chamber's members are concerned that the approach taken by OSHA will ultimately lead to less effective protection for their employees' health. At the rate of expenditure represented by the benzene standard (conservatively estimated to be at least $240 million per case of cancer avoided) it would take an annual expenditure far in excess of the Gross National Product to solve the occupational cancer problem — with nothing left over to address other societal purposes, including other causes of cancer and other health and safety problems.[2]

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[1] Booz, Allen & Hamilton, Inc., Preliminary Estimates of Direct Compliance Costs and Other Economic Effects of OSHA's Generic Carcinogen Proposal on Substance Producing and Using Industries (February, 1978). This study was directed to OSHA's still pending proposal for a generic regulation on controlling occupational carcinogens. 42 Fed. Reg. 54148 (October 4, 1977).

[2] As discussed in note 5 infra, the testimony that the standard represents an expenditure of $300 million per cancer avoided, should be revised to $240 million in light of OSHA's final cost estimates.

There are approximately 360,000 cancer deaths annually in this country, or about 1,000 per day. See OSHA, Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk, 42 Fed. Reg. 54148, 54150 (October 4, 1977).

Estimates of the portion of the overall cancer rate attributable to occupational causes range from 1% to a recent HEW estimate of 20% (attributable in large portion to asbestos). See National

The Chamber believes that more lives can be saved and serious injury prevented, by OSHA standards which offer a larger return for the resources expended. Yet unless OSHA is required to estimate the effectiveness of its standards there is no assurance that these regulations will ever even approach the maximum lifesaving potential of the resources expended.

Third, OSHA's refusal to consider the effectiveness of its standards is at variance with the positions taken by the Food and Drug Administration, the Environmental Protection Agency, the Consumer Product Safety Commission and the National Highway Traffic Safety Administration — all of which regulate the Chamber's members. If a decision of this Court were to endorse OSHA's position, and the decision were applied to other agencies, there could be disastrous effects on the level and effectiveness of regulation across the entire field of federal health and environmental control.

Finally, the Chamber is concerned that OSHA's position will lead to public disillusionment and eventually loss of support for any serious effort to alleviate the cancer problem in this country. OSHA's position is basically that all carcinogens must be regulated to the point of maximum affordable cost, regardless of the enormous degree of variation in the risks presented, which differ by more than a millionfold.[3] However, this philosophy of regulation runs

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[Footnote 2 cont.]

Cancer Institute, National Institute of Environmental Health Sciences, National Institute for Occupational Safety and Health, Estimates of the Fraction of Cancer in the United States Related to Occupational Factors (September 15, 1978), at p. 1. An estimate of 10% would involve 100 deaths a day, meaning that at an expenditure rate of $240 million per case, the total for 12 weeks would use up the Gross National Product ($2 trillion).

[3] The potency of different carcinogens varies by as much as a million times; and this difference is magnified by large differences in the levels of exposure. See respondents' brief, Addendum C.

the danger of depleting not only economic resources, but also the public support needed for effective anti-cancer measures. By refusing to distinguish between severe and remote cancer hazards, OSHA contributes to an already common public attitude that "everything causes cancer, so what's the use." Indeed, this attitude was eloquently expressed last year by a popular columnist:

> Not just aerosol deodorants and hair sprays, but the very air we breathe and the water we drink and the sunshine that warms us have all been identified as carcinogens. I even remember reading a report that linked sex with cancer. After a while, the mind refuses to accept such warnings * * *.
>
> But for most of us it's not practical to give up meat or vegetables grown with the aid of fertilizer and pesticides. We are not going to give up air or water or sunshine.
>
> What's more likely — in fact, what is already happening — is that we'll give up on the scientists who tell us these things.
>
> *It would help if scientists would tell us which substances are more dangerous than which others, or in what levels these dangerous substances can be treated as benign.*
>
> But they won't tell us these things; they say they don't know.
>
> *When nearly everything is demonstrated to be dangerous, we are forced to behave as though nothing is dangerous.* We will make our wry little jokes (calling cigarettes 'cancer sticks,' for instance) and go on as before.

Raspberry, "Those Hamburger Warnings," Washington Post, May 19, 1978 (emphasis added).

As we shall demonstrate, Mr. Raspberry's remarks are not completely accurate with regard to other federal health and environmental agencies, which do make an effort to assess the degree of public health hazard presented by a suspected carcinogen, before regulating. However, OSHA refuses to follow the other agencies' practice and now seeks this Court's endorsement for its aberrant views.

QUESTION PRESENTED

Whether OSHA must estimate the health benefits expected to result from its issuance of an occupational standard.

SUPPLEMENTAL STATEMENT OF THE CASE [4]

In 1971, OSHA adopted a standard of 10 ppm (parts per million) for occupational exposure to benzene. 29 C.F.R. §1910.1000 Table Z-2. The present proceeding involves OSHA's issuance of a regulation lowering the standard tenfold, to 1 ppm.

OSHA's proposal to lower the standard was based on studies indicating benzene had caused an excess incidence of leukemia among certain groups of workers. These studies (summarized in the opinion of the Court of Appeals, Pet. App. 8a, n. 13) involved exposures to benzene of 100 ppm and above.

At the hearing on the proposed standard, the industry argued 1) that at the levels of exposure represented by the current standard (10 ppm), there is no demonstrated risk of leukemia, and 2) that even if a risk exists, at the 10 ppm current level the risk is extremely low. In this connection, one witness (Dr. Richard Wilson of the Harvard Energy and Environment Policy Center) testified as to the level of risk, if any, present by occupational exposure to benzene at 10 ppm. He found it to be comparable to the

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[4] The Supplemental Statement is not a complete statement but rather sets forth those facts germane to the arguments presented by the Amicus.

risk that each individual in the population runs of dying in any one year from drowning or from fires and hot substances. (A 171, 172). Another comparison made by Dr. Wilson was that two weeks of exposure to benzene at 10 ppm presents a hazard equivalent to one day of air pollution in Boston or Washington, one gallon of chlorinated drinking water, or one-half bottle of wine. (A 174).

Based on OSHA's data that about 30,000 workers now have benzene exposures between 10 ppm and 1 ppm, Dr. Wilson concluded that the new standard would save at most one case of leukemia and one other cancer every six years. (A 176). Based on OSHA's preliminary cost estimates, Dr. Wilson concluded that the standard would cost at least $300 million for every life saved (a figure which should be revised to approximately $240 million in light of OSHA's final cost estimates) and might even cost more lives than it saved (since some construction work would be required, and generally one life is lost for every $20 million spent in construction). (A 81).[5]

In issuing its final standard, OSHA rejected the industry's contention that benzene had not been demonstrated to present any risk at the level of the current standard. The court of appeals accepted OSHA's conclusion on this point, which is not contested in this Court. (Pet. App. 18a).

OSHA also rejected the industry contention that it should attempt to estimate the *degree* of risk presented by exposure at the currently-required 10 ppm, and in that context assess whether the standard was "reasonably necessary" or "feasible" within the meaning of sections 3(8) and 6(b)(5) of the Occupational Safety and Health Act. 29 U.S.C. §§652(8), 655(b)(5).

[5] OSHA's final cost estimates were $187-205 million first-year operating costs, $266 million engineering control costs, and $34 million recurring annual costs (Pet. App. 17a). At an interest rate of 10%, the annual charge for the total first-year costs plus capital costs ($471 million) would be $47 million. Adding the $34 million recurring costs produces a total annual cost of $81 million. At the rate of two lives every six years or one life every three years, this produces a total of $243 million per life.

The court of appeals reversed OSHA on this point, holding that OSHA must "estimate the extent of expected benefits in order to determine whether those benefits bear a reasonable relationship to the standard's demonstrably high costs." (Pet. App. 19a).

SUMMARY OF ARGUMENT

We endorse and adopt the discussion in respondents' brief, demonstrating that OSHA's summary rejection of any serious attempt to estimate the health benefits of the benzene standard violates the requirements of the Occupational Safety and Health Act.

OSHA's position is at odds with the position taken by the other key federal agencies with responsibility for health, safety and environmental regulation — Food and Drug Administration, Environmental Protection Agency, Consumer Product Safety Commission and National Highway Traffic Safety Administration. All these agencies have performed estimations of health benefits in connection with their regulations, thus demonstrating disagreement with OSHA's position that such estimates are too uncertain to be used for regulatory purposes. Moreover, these other agencies have frequently performed health risk estimations under laws that are either similar to the Occupational Safety and Health Act, or are stricter (in the sense of requiring regulations that assure "safety" without explicit statutory authority to consider cost). In light of the other agencies' practice, OSHA cannot summarily dismiss the view that health benefit estimates can and should be performed.

It is argued that health risk estimations are too uncertain to "precisely quantify" the benefits of regulation.

However, no one has ever claimed that "precise quantification" could be provided by health risk estimation, or is necessary for regulatory purposes. The other federal agencies, when they perform risk estimations, treat them as approximations, and yet have found such approximations to be useful for regulatory purposes. Nothing in the Occupational Safety and Health Act requires precise quantification.

Moreover, there are at least two techniques for dealing with uncertainty. The witnesses in this case, as well as the other federal agencies, have compensated for the lack of precision in health risk estimates by utilizing "conservative" or "pessimistic" assumptions at key points of uncertainty — i.e., taking high estimates at uncertain points in the analysis — so as to avoid the danger of underestimating risk. Another technique (which the Chamber believes to be preferable) is to obtain from the scientists a "most probable" estimate of the level of risk together with a statement of the range of uncertainty, and then to have the decision makers apply whatever safety factors appear to be appropriate in light of that uncertainty and other relevant factors. However, OSHA does not even discuss why it rejects these techniques as ways of dealing with the problem of uncertainty in health risk estimation. Instead, OSHA simply says that health risk estimation is uncertain and therefore cannot be used. This is simply not adequate.

OSHA also contends that "cost benefit criteria" are inconsistent with the OSH Act. However, this misses the point. No one in this case has suggested that one must place a price tag on human life, and then decide whether an OSHA regulation is "worth it" in terms of that price tag. Instead, the point is that because the resources available for occupational safety and health are limited, they should be spent where they will have the maximum effectiveness in terms of lives saved. In order to determine whether its standards approximate their maximum life-saving potential, OSHA must have some rough idea as to

what the health benefit of each standard is. Only in this manner can OSHA achieve its statutory goal "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions." 29 U.S.C. §651. Standards which save lives at the rate of only one per several hundred million dollars spent will clearly not achieve anything close to the maximum life-saving potential of the available resources.

ARGUMENT

I. OSHA HAS NO VALID BASIS FOR ITS REFUSAL TO ASSESS THE EFFECTIVENESS OF THE BENZENE STANDARD

As respondents' brief demonstrates, OSHA's preamble to the benzene standard, as well as its statements and actions on other occasions, are so confusing that it is impossible to determine what the basis is for its rejection of any serious effort to estimate the health benefits of the benzene standard.

What is clear is that OSHA misunderstands the nature and utility of risk estimation when it claims: 1) that the data are not sufficiently certain to "precisely quantify" the health benefits of the regulation (Pet. App. 162a); 2) that "cost-benefit criteria" are inconsistent with the Act and would involve the impossible task of quantifying the value of life (Pet. App. 162a, OSHA Br. p. 62, n.52); and 3) that cost-benefit analysis is inappropriate as a matter of equity, because the worker bears the risk while the consumer obtains the benefit (OSHA Br. p. 47).

None of these reasons is an adequate basis for OSHA's position.

1) The existence of uncertainty is not a sufficient basis for refusal to assess the health benefits of a regulation.

OSHA's summary dismissal of the evidence concerning the miniscule degree of health benefits to be expected from the benzene regulation as "uncertain" and lacking "preci-

sion," overlooks the fact that there are at least two ways of dealing with the conceded uncertainties in risk estimations.

In both Dr. Wilson's testimony, as well as in the numerous risk assessments performed by EPA and other agencies (including EPA's assessment of benzene), the question of uncertainty is handled by making "pessimistic" or "conservative" assumptions — i.e., at points of uncertainty, the high assessment of risk is made.[6] In particular, EPA's estimation of benzene risk used a so-called linear model for extrapolating risk at low exposures from historical high-exposure data, on the ground that this model "is expected to give an upper limit to the estimated risk." (A 15).[7]

This approach to dealing with uncertainty has been described and endorsed in the recent report of the Interagency Regulatory Liaison Group (IRLG), a group consisting of the CPSC, EPA, FDA and OSHA. In this report,

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[6] An industry consultant who estimated the health benefits of the regulation at one case every 15 to 38 years, listed three "conservative assumptions" in Wilson's testimony that accounted for Wilson's higher estimation of risk:

a. *All* leukemias (not just ANLL [acute nonlymphocytic leukemia, a form specifically associated with high benzene exposures]) are benezene related.

b. For every benzene leukemia there would be another cancer at another site in the body due to benzene exposure.

c. Benzene exposure of those currently exposed to 1 to 10 ppm benezene would be far less than 1 ppm if a new standard were introduced.

(Lamm affidavit, A 34).

[7] The linear model assumes that cancer incidence varies in direct proportion to exposure. Dr. Wilson also used this model. (A 89). By contrast, other models assume that at low exposures the cancer incidence is much less than a linear model would predict. OSHA itself appears to have endorsed the linear model in its proposal for a generic policy for regulation of suspected occupational carcinogens. 42 Fed. Reg. 54148, 54167 (October 4, 1977).

the IRLG specifically addresses the question of estimating the risk of exposure to carcinogens:

> Despite the uncertainties, risk estimates can be and are being made, not only by some regulatory agencies but by other scientific bodies. *Because of the uncertainties, however, and because of the serious public health consequences that could ensue if the estimated risk were understated, it has become common practice to make cautious and prudent assumptions wherever they are needed to conduct a risk assessment.* This approach has a precedent in other areas of public health protection where similar problems arise because of gaps in knowledge. [Citation omitted] *Thus current methodologies, which permit only crude estimates of human risk, are designed to avoid understatement of the risk.*

Scientific Bases for Identifying Potential Carcinogens and Estimating Their Risks, Report of the Interagency Regulatory Liaison Group (IRLG) Work Group on Risk Assessment, Part III, "The Quantitative Estimation of Risk," 44 Fed. Reg. 39858, 39871 (July 6, 1979) (emphasis added).

The Office of Science and Technology Policy, in the Executive Office of the President, has described an alternative approach to dealing with uncertainty, which the Chamber favors. Under this approach, there would be generated a scientific estimate of the "most probable" level of risk, together with a statement of the range of uncertainty in the estimate. It would then be the function of the decision-makers to apply whatever safety factors were deemed appropriate, in light of the uncertainties in the scientific estimate, the type of health risk involved, the social costs of regulation, and any other relevant factors.[8] This ap-

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[8] The OSTP Report describes these two techniques for dealing with the problem of uncertainty:

> For each term in the equation, one could then generate a range of potential values based upon existing data. Which

proach is preferable to the "conservative assumption" technique, because it encourages the scientists to improve their techniques of estimation rather than freezing the evolving science of risk estimation into a particular format, and it brings out into the open policy forum the choices that must be made regarding the size of the margin of safety to be built into regulatory decisions — rather than hiding these choices in an often high technical scientific analysis.[9]

[Footnote 8 cont.]

of these values, however, should be entered into the equation for an accurate asessment of overall risk? One approach is to use the high risk estimate for each term in the equation. This results in the most extreme estimate possible for risk to humans. Another approach is to use the most likely value for each term, including confidence intervals which express the precision of each estimate. This latter approach generates the risk estimate which has the greatest probability of being accurate and which also makes clear the uncertainty involved.

Office of Science and Technology Policy, Executive Office of the President, Identification, Characterization, and Control of Potential Human Carcinogens: A Framework for Federal Decision-Making (February 1, 1979), at p. 18.

[9] A recent article by Judge Bazelon, discussing the question of risk estimation, stresses the importance of keeping value judgments out of the scientific component of the decision, so that they may be explicitly acknowledged and discussed by the policy-makers. This, we believe, is the most important reason why the "most probable" risk approach is preferable to the "conservation assumption" technique:

> The growing use of analytic tools such as cost-benefit analysis magnifies the chance that unrecognized value judgments will creep into apparently objective assessments. Even the most conscientious effort by experts,not to exceed their sphere of competence may be inadequate to safeguard the validity of the decision-making process. * * * *
>
> Courts, standing outside both scientific and political debate, can help to make sure that decision-makers articulate the basis for their decisions. In the scientists' realm — the sphere of fact — courts can ask that the data be described, hypotheses articulated, and, above all, in those areas where we lack knowledge, that ignorance be confessed. In the political realm — the sphere of values — courts can ask that de-

Of course, it is not for this Court to choose between various forms of risk analysis. Rather, the choices must be made by the various regulatory agencies that deal with health and safety issues. However, here OSHA has not even addressed the issues, but instead has summarily stated that it cannot accept "uncertainty." This is simply not an adequate basis for what OSHA has done.

In the area of health and environmental regulation, the courts have stressed that the government must act at the "frontiers of knowledge"; that substantial uncertainties are necessarily involved; but that uncertain data may nevertheless be the basis for action. *Ethyl Corp. v. EPA*, 541 F.2d 1, 24-29 (D.C. Cir 1976) (en banc), *cert. denied* 426 U.S. 941 (1976). See also, OSHA's proposal for a generic carcinogen policy, 42 Fed. Reg. 54148, 54153 (October 4, 1977), discussing its obligation to regulate on the basis of uncertain evidence. The OSH Act itself emphasizes this point, by directing OSHA to set standards on the basis of the "best available evidence." 29 U.S.C. §655(b)(5). With specific reference to carcinogen risk assessment, the IRLG report makes the same point by stating that with present knowledge, assessment of cancer risk provides "a rough estimate of the magnitude of the cancer risks which may be useful in setting priorities among carcinogens and in obtaining a very rough idea of the

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[Footnote 9 cont.]

cision-makers explain why they believe that a risk is too great to run or why a particular trade-off is acceptable. *Perhaps most important, in the nether realm, at the interface of fact and value, courts can help assure that the value component of decisions is explicitly acknowledged, not hidden in quasi-scientific jargon.*

Bazelon, Risk and Responsibility, 65 A.B.A.J. 1066, 1068 (July, 1979) (emphasis added). The degree of conservativism in a regulatory decision is a question in the "political realm" or the "sphere of values", as Judge Bazelon puts it. Thus it should be kept out of the scientific analysis, which should be confined to an estimation of the most probable risk and the range of uncertainty.

magnitude of the public health problem posed by a given carcinogen." IRLG Report, 44 Fed. Reg. at 39872.

When a "rough estimate" is that the regulation would cost $240 million per life saved, the regulation would be unreasonable even if the estimate were overstated by a large multiple (and it may be understated [10]). OSHA cannot avoid the problem by summary and irrelevant references to "uncertainty" and the impossibility of "precise quantification."

2) The conceded impossibility of quantifying the value of human life is not an adequate basis for refusing to assess the effectiveness of a health regulation.

OSHA's decision hints that one of its reasons for refusing to assess the effectiveness of the benzene standard is the impossibility of quantifying the value of human life. (Pet. App. 163a). The same suggestions lurks in OSHA's statement that "cost benefit criteria" are impermissible under the Act. (Pet App. 162a). The Government's brief makes this point more explicitly (at pp. 62-63 n. 52).

In fact, this argument totally misses the point. No one in this proceeding has suggested that it is possible or even desirable to place a value on human life. Instead the point made was that, since resources are limited, the expenditure of several hundred million on this regulation would inevitably mean that several hundred million would not be available to spend on other health and safety regulations; and that if several hundred million spent elsewhere would save more lives, then its expenditure here would mean that the overall health and safety effort would be *less* effective and save *fewer* lives.[11]

[10] Other estimates are that the regulation will save one life every 15 to 38 years, or one life every 83 years. (A 34, A 35).

[11] Dr. Zeckhauser, an economist, testified that much of the cost of the standard represents resources that would otherwise be available for other societal purposes, including protection of health and safety in other areas:

> If a private corporation is in a 50 percent marginal tax bracket, for example, one half of any reduction in profits due to expenditures entailed by regulations will be borne directly by the taxpaying public as a whole. A further fraction would be borne, of course, given reduced taxes on earnings eventually going to shareholders in the form of dividends or capital gains. Of course, much if not most, of the expenditure will not come out of profits. Some will come out of the wages of workers. More will be passed on in the form of higher prices, in general the less elastic is the demand for the product. For example, since the price elasticity for gasoline is low, additional costs in gasoline production will be mostly absorbed through higher prices.
>
> The economic costs we are talking about represent real resources that could be devoted to other purposes in society. For example, in computing the economic costs of the benzene standard, we should recognize that doctors administering tests for benzene exposure to workers will not be available to deliver other medical services. The workers and machines producing monitoring equipment will be taken away from the production of other equipment that might have been used either to save lives, or to serve any other purpose of society.

(A 142).

In other words, it is just because the value of life is infinite, that it is vitally important to spend our limited health and safety dollars in those areas where they will save the most lives. In order to do this, we must have some rough idea of the life-saving potential of any health or safety regulation that is proposed.

The point was summarized in the testimony of Dr. Zeckhauser:

> [W]hen attempting to accomplish some end such as protecting human health, we should direct economic resources where they accomplish the most. If the expenditure of an additional $1,000,000 would save five lives on the highway, but the same expenditure on plant safety would only save one life, then if we chose the plant safety expenditure over the

highway expenditure, we would in effect be sacrificing lives.

(A 140).[12]

OSHA's suggestion that it is impossible to quantify the value of human life is correct, but totally irrelevant. In fact, OSHA has given no reason why it cannot and should not attempt to maximize the effectiveness of the occupational safety and health dollar, and thus best serve the purpose of the OSH Act "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions." 29 U.S.C. §651.[13]

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[12] Dr. Zeckhauser made it plain that estimating the effectiveness of a health regulation does *not* require putting a value on human life:

> I should be explicit. I am not arguing that a cost-benefit approach be employed in formulating policy on occupational safety and health. Such an approach would require that a dollar price tag be attached to a life saved. The value of the lives saved would then be weighed against the resources invested to find the program that had the highest net value. The major objection to this approach is that there is simply no widely accepted precedure for determining the value of lives in contexts such as these.
>
> Fortunately, there is an alternative approach, called cost-effectiveness analysis, that enables us to establish priorities in programs for saving lives. The guiding principle of cost-effectiveness analysis is that for whatever level of resource expenditure we are undertaking, we should attempt to gain the maximum possible level of effectiveness. * * * * The criterion for effectiveness in the occupational health area would be health or lives preserved.

(A 137).

[13] Dr. Zeckhauser conceded in his testimony that OSHA might disclaim responsibility for consistency with other government health and safety agencies, in terms of the level at which standards are considered to be cost-effective. (A 140). However, as Dr. Zeckhauser pointed out, OSHA should "make every attempt to be consistent across the broad sweep of problems encompassed by occupational health and safety." *Ibid.* But without knowing the cost-effectiveness of the benzene standard, OSHA has no way of knowing whether the resources spent there might be more effectively spent and save more lives in some other occupational area.

3) The allegedly inequitable distribution of risk and benefit is an inadequate basis for refusing to estimate the extent of health benefits.

The Government's brief (at p. 47, n.38), although not the OSHA decision, argues that cost-benefit analysis is inappropriate because in the occupational context the worker bears all the risk, while the consumer obtains the benefit (in the form of a lower price). This, the Government argues, is unlike the consumer area, where a risky product (such as a sharp kitchen knife) at least gives the consumer some benefit along with the risk.

However, this argument is also irrelevant. The purpose of estimating the extent of health benefits for occupational regulations is to maximize the number of lives saved by occupational regulations. It is not a question of balancing worker risk against consumer benefit. Rather, it is a question of maximizing worker benefit. Thus the argument of an inequitable distribution of cost and benefit is simply irrelevant.

II. THE PRACTICE OF OTHER FEDERAL AGENCIES DEMONSTRATES THAT THE BENEFITS OF HEALTH AND SAFETY REGULATION CAN BE ASSESSED WITH SUFFICIENT CERTAINTY FOR REGULATORY PURPOSES, AND THAT SUCH ASSESSMENT IS CONSISTENT WITH THE PURPOSES OF HEALTH AND ENVIRONMENTAL LAWS SIMILAR TO THE OSH ACT.

Among the federal health and environmental regulatory agencies, OSHA stands alone in refusing to assess the cost-effectiveness of its regulations. The Food and Drug Administration, the Environmental Protection Agency, the Consumer Product Safety Commission, and the National Highway Safety Administration, have all found it useful to estimate, generally in quantitative terms, the effectiveness of their regulations. Recognizing the uncertainties involved in these estimates, these agencies have nevertheless

found them to be useful for regulatory purposes. In particular, these agencies have attacked the problem of uncertainty by utilizing the "conservative assumption" technique — that is, resolving uncertainties in the direction of the higher health risk, so as to avoid understatement of risk.

The OSH Act requires OSHA to take into consideration "experience gained under this and other health and safety laws." 29 U.S.C. §655(b)(5). There is no evidence that OSHA has done so. The experience of other federal agencies shows that health benefit estimations are sufficiently reliable to be used for regulatory purposes; OSHA cannot dismiss this experience with the conclusory statement that estimates of health benefits are "extremely uncertain" and cannot provide "precise calculations." (Pet. App. 162a, 163a).

In addition, as we shall demonstrate, the various statutory authorities under which other federal agencies have estimated the health benefit of their regulations are frequently similar to the OSH Act (in the sense of requiring regulations to be "feasible" or "practicable"), and in some cases are even stricter than the OSH Act (such as the Delaney Clause).

While OSHA argues that its statute is different, because of Congress' overriding concern for worker safety and health, the statutory authorities of the FDA, EPA, CPSC and NHTSA also exhibit overriding concern for the safety of the food supply and consumer products, for environmental protection and for traffic safety. Nevertheless, these other agencies have found that estimating the effectiveness of their regulations is consistent with Congressional intent. The experience of other agencies, at the very least, destroys any claim made by OSHA that its unique view is entitled to special deference from the courts.

We shall now summarize the practice of the FDA, EPA,

CPSC and NHTSA in estimating the health benefits of their regulations, in each case also summarizing the pertinent statutory authorities under which these estimations have been made and comparing these authorities to the OSH Act.[14]

Food and Drug Administration

Despite statutory authority which, unlike the OSH Act, on its face would appear to contain no room for risk estimation, the FDA has estimated the magnitude of risk in connection with its regulatory actions. Indeed, the FDA has recently proposed to adopt risk estimation as part of formal Agency policy.

The Delaney Anti-Cancer clause of the Federal Food, Drug and Cosmetic Act, forbids the FDA from approving food additives or animal drugs shown to cause cancer in man or, by appropriate tests, in animals.[15] Both the language and the legislative history of the Delaney Clause demonstrate that Congress thought that cost could not be a consideration justifying carcinogenic food additives. Moreover, the FDA regards the Delaney Clause as a "particularization of the general safety sections of the act." 44 Fed. Reg. 17070, 17074 (March 20, 1979). Thus the FDA interprets its general obligation to disapprove a food additive if the data fails to show that use of the additive "will be safe," [16] as meaning that the additive must be "safe in all

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[14] The following discussion is not, of course, intended to imply endorsement of any particular regulatory decision. Rather, the point is that agencies other than OSHA are making an attempt to estimate risk by some method or another, while OSHA claims that the attempt cannot and should not be made.

[15] 21 U.S.C. §§348(c)(3)(a) (food additives), 376(b)(5)(B) (color additives), and 360b(d)(l)(H) (animal drugs).

[16] Federal Foods, Drug and Cosmetic Act §409(c)(3)(A), 21 U.S.C. §348(c)(3)(a).

respects — including safe from carcinogenicity." 44 Fed. Reg. 17070 at 17074 (March 20, 1979). Cost is not a consideration under these provisions.

Nevertheless, the FDA has found room in this stringent statutory scheme to accommodate the quantitative estimation of the magnitude of risk posed by carcinogenic chemicals. In its proposed regulation of saccharin (which was aborted by special legislation), the FDA estimated "that the lifetime ingestion of the amount of saccharin in one diet beverage per day results in a risk to the individual of somewhere between zero and 4 in 10,000 of developing cancer of the bladder." 42 Fed. Reg. at 20001 (April 15, 1977).

The FDA estimated the number of resulting cancers on the basis of the conservative assumption that "everyone in the United States drank one [diet] beverage a day." *Ibid.* The FDA explained that it did not regard current scientific methods as being capable of determining the "exact risk," but that "techniques are available for estimating the upper limits of the risk." *Ibid.*

Recently the FDA has proposed regulations which would formalize its commitment to quantitative risk estimation. This proposal arises in the context of the provision of the Federal Food, Drug and Cosmetic Act regarding animal drugs. 21 U.S.C. §360b. This provision prohibits approval of a drug which induces cancer in man or animals, unless "no residue" of the drug is found in edible portions of the animal by approved methods of examination. 21 U.S.C. §360b(d)(1)(H). FDA's recent proposal is to approve those methods of examination which are sensitive enough to detect drug residues creating *no more than a one in a million lifetime risk of cancer for the consumer.* 44 Fed. Reg. at 17111 (March 20, 1979 (proposing 21 C.F.R. §§500.89(f), 500.90(a)). The proposed regulations employ the technique of conservative assumptions to avoid understatement of risk in the estimation of whether the one-in-a-million risk is present. Thus the proposed regulations require "linear extrapolation" on the ground that it is "least likely to underestimate risk";[17] they also assume that "the maximum concentration of residues potentially undetected in edible tissues is consumed every day over a lifetime";[18] and they use various other "conservative procedures and assumptions" to help compensate for possible underestimation. 44 Fed. Reg. at 17093 (March 20, 1979).

Another example of FDA action in estimating health risk is found in its proposal of a temporary tolerance for polychlorinated biphenyls (PCB's) in fish. Section 406 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §346, authorizes the FDA to limit the quantity of environmental contaminants in food "to such extent as [it] finds necessary for the protection of public health." In establishing the level of contamination to be tolerated, FDA must take into account "the extent to which the use of such [contaminating] substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected * * *." *Ibid.* In short, the statute is much like the OSH Act, in establishing two criteria for action: 1) health, and 2) feasibility [i.e., the extent to which contamination "cannot be avoided"].

In its recent action reducing the tolerance for PCB's from 5 to 2 ppm, the FDA estimated "the upper limit on the lifetime risk of cancer for heavy consumers of fish most affected by the tolerance" for the three levels suggested by parties to the proceeding: 5 ppm, 2 ppm and 1 ppm. The FDA concluded that the lifetime risk is "9.8 incidences of cancer per 100,000 of the population, assuming the tolerance is 5 ppm; 7.2 per 100,000 assuming the tolerance is 2 ppm; and 4.4 per 100,000 assuming the tolerance is 1 ppm." 44 Fed. Reg. 38330, 38333 (June 29, 1979).

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[17] 44 Fed. Reg. at 17089 (March 20,1979).

[18] 44 Fed. Reg. at 17092 (March 20, 1979).

Because of uncertainties in the data, the FDA stated that the utility of the risk assessment is "extremely limited" and that it did not provide a basis for "precise quantification" of the amount of risk reduction from the reduction in PCB levels. Nevertheless, the FDA concluded that the risk assessment was "illustrative of the toxicological rationale for reducing the tolerance for PCB's in fish." *Ibid.* Moreover, the FDA was able to conclude that for average consumers, the additional health protection in moving from 2 ppm to 1 ppm (as some parties to the proceeding had urged) would be "slight" and would thus not justify the significantly greater impact that such a tolerance would have on food availability (estimated to be approximately $16 million). 44 Fed Reg. 38330 at 38335, 38333 (June 29, 1979).

In short, under a statute much like the OSH Act, the FDA concluded that although its "paramount concern" is "protection of the public health," it must nevertheless "ensure that the direct economic consequences of the tolerance (in this case, decreased sales and employment in the commercial fishing industry) will not be disproportionate to the increased degree of public health protection accomplished by the tolerance." 44 Fed. Reg. 38333, 38334 (June 29, 1979). Pursuant to that responsibility, the FDA performed a quantitative estimation of the degree of public health benefit from the various proposed levels of regulation, and while recognizing the uncertainties inherent in the estimation, nevertheless utilized it in arriving at its final judgment as to the proper level of regulation.

Environmental Protection Agency

EPA's practice with respect to suspected carcinogens is set forth in "Health Risk and Economic Impact Assessments of Suspected Carcinogens: Interim Procedures and Guidelines," 41 Fed. Reg. 21402 (May 25, 1976). This document requires that where EPA proposes to take regulatory action against a suspected carcinogen, a "risk analysis" shall be performed, which will estimate "excess lifetime incidence, or average excess cancer rates * * *." *Id.*, at 21405. The document provides that "[t]he uncertainty in the data and extrapolation techniques should be clearly indicated." *Ibid.* In addition, EPA points out that "the risk estimates should be regarded only as rough indications of effect." *Id.*, at 21404. Nevertheless, EPA's policy is to perform these risk estimates where this is consistent with its statutory authorities.

The EPA experience confirms 1) that risk estimation for carcinogens, while concededly not a precise science, is nevertheless sufficiently reliable for regulatory purposes if used with an appreciation of its limitations, and 2) that the statutory concepts of "safety" and "feasibility" are consistent with the use of risk estimation as an element in the regulation of suspected carcinogens.

Under the Safe Drinking Water Act, 42 U.S.C. §300f et seq., EPA has authority to set "national interim primary drinking water regulations." These regulations are required to "protect health to the extent feasible, using technology * * * which the Administrator determines [is] generally available (taking costs into consideration) * * *." §1412(a (2), 42 U.S.C. §300g-1(a)(2). Like the OSH Act, the overriding purpose of the Safe Drinking Water Act is to protect health but with some allowance for feasibility.[19]

EPA has proposed regulations governing the concentrations of trihalomethanes in drinking water, on the basis of a suspected cancer risk. 43 Fed. Reg. 5756 (Feb. 9, 1978). These regulations were proposed at a level which EPA determined to be "as low as economically and technologically feasible." 43 Fed. Reg. 5763. However, because the proposed regulations would require very substantial expenditures (annual expenditures, including capital charges,

[19] H.R. Rep. No. 93-1185, 93rd Cong. 2d Sess. at 9.

operation and maintenance, of between $57 and $145 million), EPA also estimated the extent of the cancer risk presented by trihalomethanes in drinking water. EPA concluded that "a statistical extrapolation of the data indicates that a life-long exposure to those contaminants in drinking water may account for 200 excess fatalities per year nationwide. * * *. Other studies would indicate even higher risks." 43 Fed. Reg. at 5769.

EPA's estimates were obtained from a report of the National Academy of Sciences, which "suggested that the risk could be approximated with available extrapolation techniques and, applying such techniques, derived risk estimates for the identified carcinogens." 43 Fed. Reg. at 5768. Referring to the Academy's report, EPA stated that although "it is not possible to project with accuracy from risk estimates to absolute numbers of cancers in a human population", nevertheless the "approximate impact" of the standard had been estimated. 43 Fed. Reg. at 5761.

Section 303 of the Clean Water Act, 33 U.S.C. §1313, requires the States to establish water quality standards subject to EPA review and approval. Under section 303, EPA has also performed risk estimates for carcinogens.

Section 303 provides that water quality standards must "protect the public health or welfare, enhance the quality of the water and serve the purposes of the Act." §303(c)(2), 33 U.S.C. §1313(c)(2). EPA is required to establish "water quality criteria", which reflect "the kind and extent of all identifiable effects on health" which may be expected from the presence of pollutants in the water. Clean Water Act, §304(a), 33 U.S.C. §1314(a). A standard is then set for a particular body of water depending on the use anticipated; if the anticipated use involves human use of the water (drinking, recreation or eating fish from the water), then the standard must be set to "protect the public health" (§303(c (2)), taking into account the "water quality criteria."

In a recent notice, EPA has proposed water quality criteria designed to assist in the process of setting water quality standards. 44 Fed. Reg. 15926 (March 15, 1979). In the case of carcinogenic water pollutants, the EPA criteria "estimate ambient water concentrations which * * * represent various levels of incremental cancer risk." 44 Fed. Reg. at 15929.

In the case of benzene, EPA stated that "the recommended concentration of benzene in water for maximum protection of human health is zero." 44 Fed. Reg. at 15936. However, "[b]ecause attaining a zero concentration level may be infeasible in some cases and in order to assist the Agency and States in the posible future development of water quality regulations," EPA estimated "the concentrations of benzene corresponding to several incremental lifetime cancer risk levels." *Ibid.* Specifically, EPA estimated the concentrations of benzene which would pose a lifetime risk to persons drinking the water and eating fish taken from the water of one in 100,000, one in one million, and one in ten million. *Ibid.*

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) provides that a pesticide may not be registered if its use will result in "unreasonable adverse effects on the environment", a phrase that is defined as "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide." 7 U.S.C. §§136(bb), 136a(c)(5), 136d(b).

EPA's present practice in the pesticide area is illustrated by its recent actions in the cases of the pesticides amitraz and chlorobenzilate.

EPA concluded that the use of amitraz on pears and apples "might pose a very small risk of cancer to certain exposed groups." 44 Fed. Reg. 2678 (January 12, 1979). It further concluded that there is "an indication of possible

significant benefit from the use of amitraz on pears" but "little or no benefit from its use on apples." *Ibid.* Accordingly, EPA granted a conditional registration for pears (on the basis of "substantial benefits and very small risks") and denied registration as to apples. 44 Fed. Reg. 32736 (June 7, 1979).

In reaching this decision, EPA estimated the lifetime risks for individuals consuming amitraz-treated apples and pears (two chances in a million) and the lifetime cancer risks for workers applying amitraz to pears and apples (one in ten thousand for apples, six in one hundred thousand to one in ten thousand for pears). 44 Fed. Reg. at 2681.

Commenting on these risk estimations, EPA stated that they are "neither scientific certainties nor absolute upper limits, but are used by the Agency only as rough approximations of potential health risks." *Ibid.*

EPA recently decided to cancel the registration of chlorobenzilate for uses other than citrus uses in certain states; as to these citrus uses, registration was allowed subject to restrictions on handling of the pesticide. 44 Fed. Reg. 9548 (Feb. 13, 1979). In balancing the risks and benefits, EPA estimated the magnitude of the lifetime cancer risk through dietary exposure in Florida and in the rest of the United States (the estimated risk ranges from 0.5 to 7.0 in a million). 44 Fed. Reg. at 9556, 9557.

During the proceedings leading to EPA's decision, an environmental organization had criticized the cancer risk assessment on the ground that it did not take into account the heterogeneity of the human population, and possible synergistic effects of chlorobenzilate with other chemicals in the environment. EPA's response was that it would use the "conservative assumption" technique to avoid underestimation resulting from these uncertainties:

> Because uncertainties such as synergism and heterogeneity exist, the Agency used the most conservative model and test results from the most sensitive group of test animals to extrapolate to humans the cancer risk associated with chlorobenzilate.

44 Fed. Reg. at 9553.

EPA also has the authority to establish limits on radiation exposures outside the boundaries of nuclear facilities. Reorganization Plan No. 3, 1970, §2(5). These standards are authorized by the Atomic Energy Act, which requires these standards to "protect health or to minimize danger to life or property." 42 U.S.C. §2201(b). This language has been interpreted by the Nuclear Regulatory Commission and by EPA to require risk-benefit balancing in the establishment of radiation protection standards. See 10 C.F.R. §20.1(c) (NRC interpretation); 40 Fed. Reg. 23420, 23421 (May 29, 1975) (EPA interpretation).

In proposing its environmental radiation standards, EPA calculated the expected health benefits and the costs, estimating "the cost of implementing the proposed standards for these long-lived radioactive materials to be less than $100,000 per potential case of cancer, leukemia, or serious genetic effect averted." 40 Fed. Reg. at 23422. In the final regulation, which adopted the protection levels proposed, EPA rejected criticisms that its risk estimates were either too low or too high. In particular, EPA stated that "the weight of currently available scientific evidence supports the continued use of a linear, nonthreshold model for deriving standards to protect public health." 42 Fed. Reg. 2858, 2859 (Jan. 13, 1977) (promulgating 40 C.F.R. Part 190).

Consumer Product Safety Commission

The CPSC operates under a statutory mandate to protect the consumer from "unreasonable risks of injury" associated with consumer products. 15 U.S.C. §2051(b)(1). Each standard must be "reasonably necessary" to prevent

or reduce such risk. 15 U.S.C. §2056(a). This compares to the OSH Act, which is aimed at "material" impairment of health and requires that standards be "feasible" and "reasonably necessary." 29 U.S.C. §§652(8), 655(b)(5).

The CPSC's recent standard for walk-behind power lawn mowers illustrates its use of risk estimation in complying with its statutory mandate. In this standard, the CPSC estimates that about 150,000 injuries associated with power lawn mowers occur each year, about 60,000 of which are treated in emergency rooms. 44 Fed. Reg. at 9992 (Fed. 15, 1979). The CPSC further breaks down the number of injuries expected to be saved by each of the major requirements of the standard; estimates the dollar savings exclusive of pain and suffering; estimates the total retail price increase resulting from the standard ($189 million); and concludes that the standard is reasonably necessary to reduce an unreasonable risk of injury. 44 Fed. Reg. at 9996-7 (Feb. 15, 1979).

The CPSC also has authority under the Federal Hazardous Substances Act to ban "hazardous substances", defined as substances which "may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." 15 U.S.C. §1261(f)(1)(A). In its notice declaring tris — a chemical used as a flame retardant in children's sleepwear — to be a banned hazardous substance, the CPSC relied on three risk assessments concerning the potential of tris to cause cancer. 42 Fed. Reg. 18850, 18851 (April 8, 1977). These estimates were prepared by the Commission's Bureau of Biomedical Science, by the Environmental Defense Fund, and by researchers at the Department of Biochemistry at Berkeley. The Bureau's high estimate was 5100 cases per million male children exposed. The highest estimate (from Berkeley) was 17,000 cases per

million children exposed. *Ibid.* In view of the very high range of risk estimates, the Commission took emergency action.

National Highway Traffic Safety Administration (NHTSA)

In its "Five Year Plan for Motor Vehicle Safety and Fuel Economy Rulemaking", NHTSA has stated that among the factors it considers in establishing motor vehicle safety standards are "anticipated costs to consumers and industry" and "lifesaving potential of a safety standard." 43 Fed. Reg. 11100, 11101 (March 16, 1978). An excellent example of NHTSA's practice in this regard is found in its air bag standard, which sets forth the "Fatalities Prevented Per Year" and the "Injuries Prevented Per Year" under each of the various occupant restraint systems under consideration, with cost estimates for the full front air bag system (one of the options chosen in the final regulation). 42 Fed. Reg. 34289, 34298-99 (July 5, 1977).[20]

NHTSA's statutory mandate is similar to OSHA's. Like OSHA, NHTSA's overriding mission is to protect health and safety: to "reduce traffic accidents and deaths and injuries to persons resulting from traffic accidents." 15 U.S.C. §1381. However, the standards must be "reasonable, practicable and appropriate." 15 U.S.C. §§1392(f), 1391(2). Judge Stevens' description of NHTSA's authority fits almost exactly to OSHA:

> Although I recognize that safety is the 'overriding consideration in the issuance of standards' under this Act, the statute requires respondent to consider

[20] A more detailed breakdown of NHTSA's cost-benefit analysis of the air bag standard is set forth at 41 Fed. Reg. 31860 (July 30, 1976). Using the highest NHTSA cost estimate, the full front air cushion system, adopted in the final regulation, is estimated to save lives at a cost just under $300,000 per life (leaving out of the estimate any allocation of cost to the substantial number of injuries prevented by the regulation).

whether a proposed standard is 'reasonable, practicable and appropriate' before it is prescribed.

H & H Tire Company v. Department of Transportation, 471 F.2d 350, 357 (7th Cir. 1972) (Stevens, J., concurring). But unlike OSHA, NHTSA interprets this mandate to require it to estimate the health and safety benefits of its regulations.

CONCLUSION

Because OSHA has refused to estimate the expected health benefits for the benzene standard, the judgment of the Court of Appeals setting the standard aside should be affirmed.

Respectfully submitted,

Of Counsel:

STEPHEN A. BOKAT
WILLIAM L. KOVACS
National Chamber Litigation Center
1615 H Street, N.W.
Washington, D.C. 20062

ROBERT V. ZENER
Pepper, Hamilton & Scheetz
1776 F Street, N.W.
Washington, D.C. 20006

Attorneys for Amicus Curiae
Chamber of Commerce of the United States

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